

IEC60601-1-8 Compliant MCU Based Medical Alarm Reference Design With Supercapacitor Backup



Description

This reference design is an IEC60601-1-8 compliant medical alarm system utilizing the MSPM0G1507 or MSPM0G3507 microcontroller (MCU) to offer primary alarm, backup alarm, and visual alarm functionality. The MCU reads audio from internal or external flash and outputs the digital-to-analog converter (DAC) waveform to the audio amplifier. During system power loss, the backup piezo buzzer and MCU with integrated real time clock (RTC) remain powered from a supercapacitor.

Resources

TIDA-010264	Design Folder
MSPM0G1507	Product Folder
MSPM0G3507	Product Folder
TPS61094	Product Folder
TPA6211A1	Product Folder



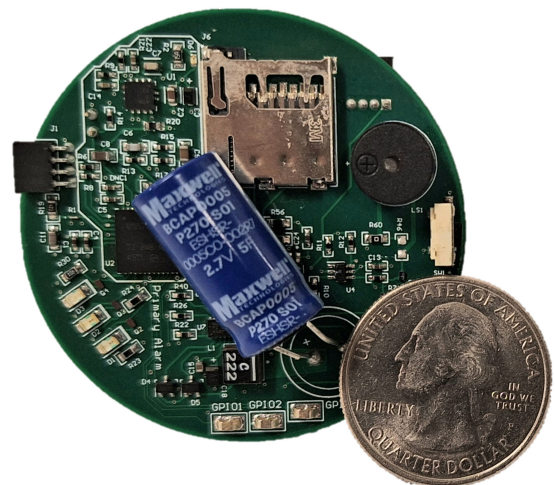
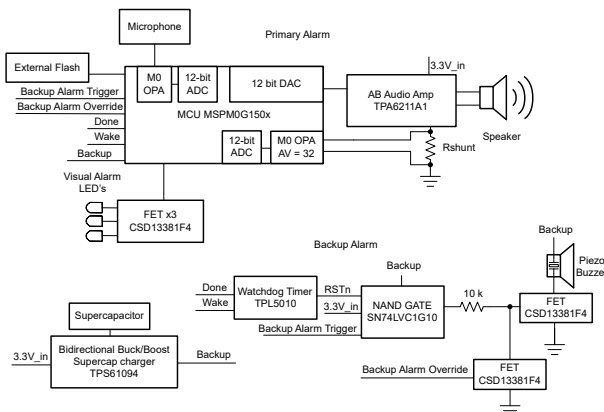
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Features

- IEC60601-1-8 compliant primary, backup, and visual alarm system
- Capability to play standard and custom alarms with 128kB internal flash and external flash options
- 12-bit, adjustable frequency (capable of 48 kHz+) high-fidelity audio using integrated DAC
- Over 3 minute backup alarm using supercapacitor backup
- 3 visual alarm LEDs: high, medium, and low priorities
- 49-mm diameter - small form factor for space-constrained medical applications

Applications

- [Infusion pump](#)
- [Multiparameter patient monitor](#)
- [Ventilators](#)
- [Dialysis machine](#)
- [Anesthesia delivery systems](#)



1 System Description

Medical alarm systems are a required subsystem for most medical devices, especially those used in an intensive care unit (ICU). For patient safety, these medical devices must comply with the requirements established by the International Electrotechnical Commission (IEC). The IEC60601-1-8 standard details the necessary alarm-related elements for these systems including a primary alarm, a redundantly powered backup alarm, and a visual alarm indicator. This design provides an IEC60601-1-8 medical alarm utilizing the MSPM0G1507 microcontroller (MCU) to offer primary alarm, backup alarm, and visual alarm functionality. Figure 2-1 depicts the design block diagram.

2 System Overview

2.1 Block Diagram

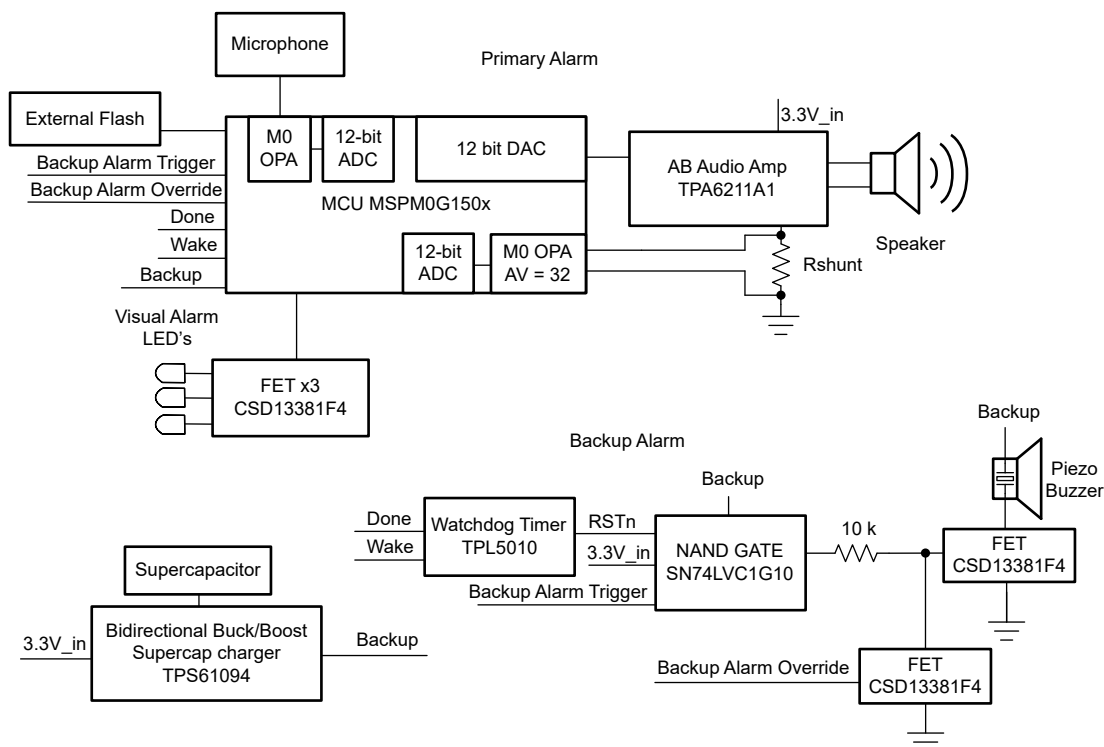


Figure 2-1. TIDA-010264 Block Diagram

2.2 Design Considerations

2.2.1 Primary Alarm Circuit - Current Sensing

Figure 2-2 shows the primary alarm circuit using the TPA6211A1 class AB audio amplifier.

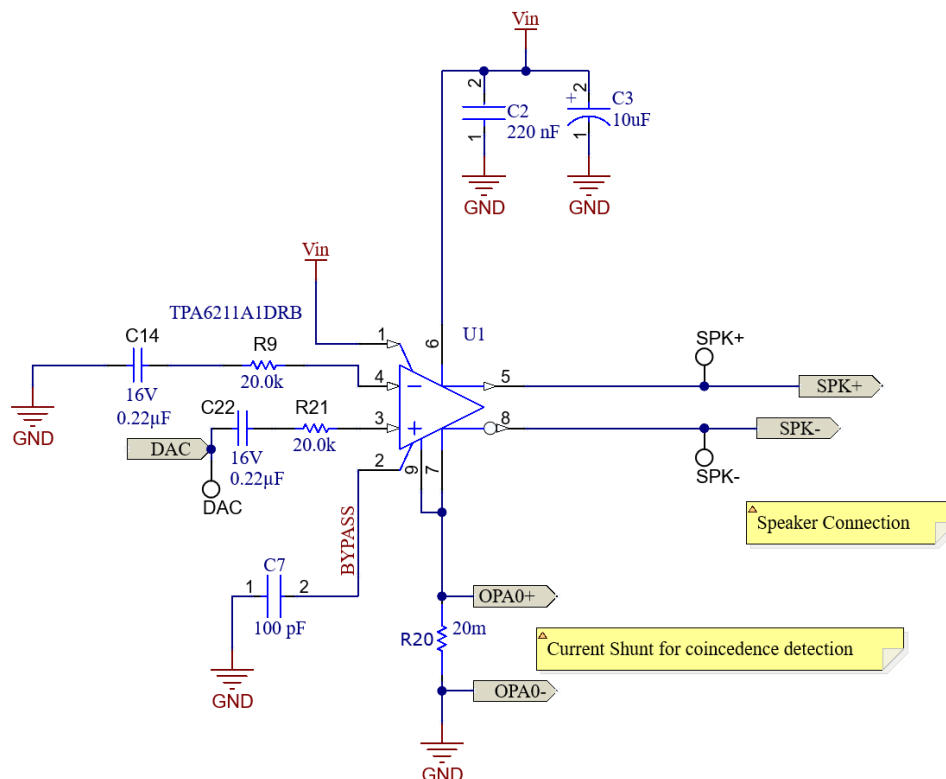


Figure 2-2. Primary Alarm Amplifier Circuit

Low-side current sensing is implemented using shunt resistance R20 that is voltage-amplified by the internal op amp of the MSPM0 MCU with an internally-configured noninverting gain of 32. A 12-bit ADC then digitizes this value. This data can be used to detect if the speaker is connected when audio is played on the audio amplifier. During testing, about 0.6 A of maximum current was measured with a high-alarm state, 4-Ω speaker, and 3.3-V input voltage. See Figure 3-5 for the analog current waveform.

For shunt resistance, a 20-mΩ shunt was tested, leading to approximately 496 ADC steps with 0.6 A through the shunt. If additional gain is needed, a larger shunt resistance can be used, or external resistors can be used to set the gain.

Equation 1 shows the maximum ADC output voltage swing and ADC step count given the shunt resistance.

$$V_{\text{shunt}} = R_{\text{shunt}} \times I_{\text{shunt}}$$

$$V_{\text{ADC}} = 32 \times (R_{\text{shunt}} \times I_{\text{shunt}})$$

$$\{R_{\text{shunt}} = 20 \text{ m}\Omega, I_{\text{shunt_max}} \cong 0.6 \text{ A}\} \rightarrow V_{\text{ADC_max}} = 0.384 \text{ V}$$

$$\text{Max \# ADC Steps} = \frac{V_{\text{ADC_max}}}{V_{\text{REF}}} \times 4095$$

$$\{V_{\text{REF}} = 3.3 \text{ V}\} \rightarrow \text{Max \# ADC Steps} = 496$$

(1)

2.2.2 Microphone Circuit - Coincidence Detection

For additional feedback from the environment such as ambient noise or acoustic feedback from the primary alarm, an optional microphone was added. Figure 2-3 shows the microphone circuit along with the connections to the configured op amp of the MSPM0.

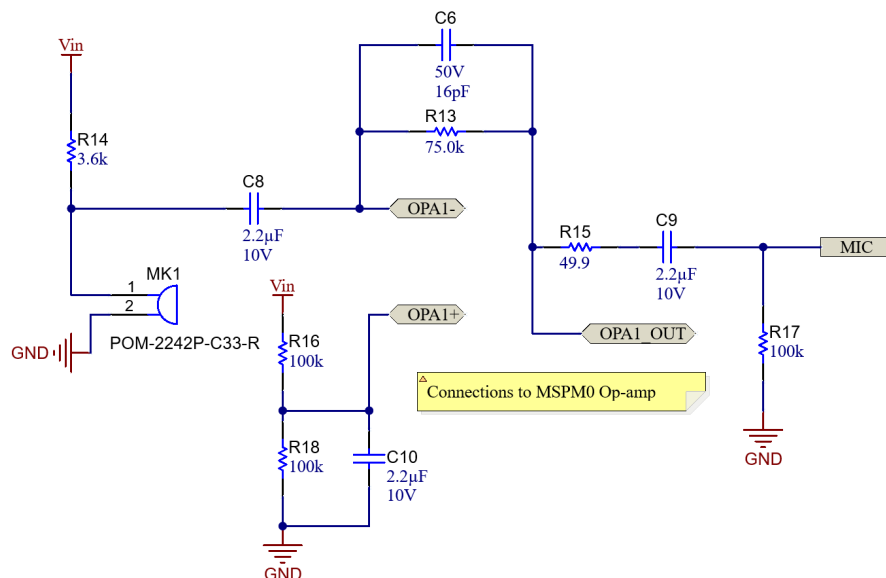


Figure 2-3. Microphone Circuit

2.2.3 Backup Alarm Circuit

Figure 2-4 shows the backup alarm circuit. This circuit triggers the backup alarm if the primary power is lost, or if the MCU triggers the alarm. The TPL5010 external watchdog timer resets the MCU if the system stops responding. If the secondary alarm override Q5 gate is pulled high from the MCU, then the backup alarm is turned off, regardless of the other inputs to the NAND gate U4. This allows for the MCU to take full control of the alarm circuit when necessary, for example, allowing for the alarm to be disabled after the required 3 minutes.

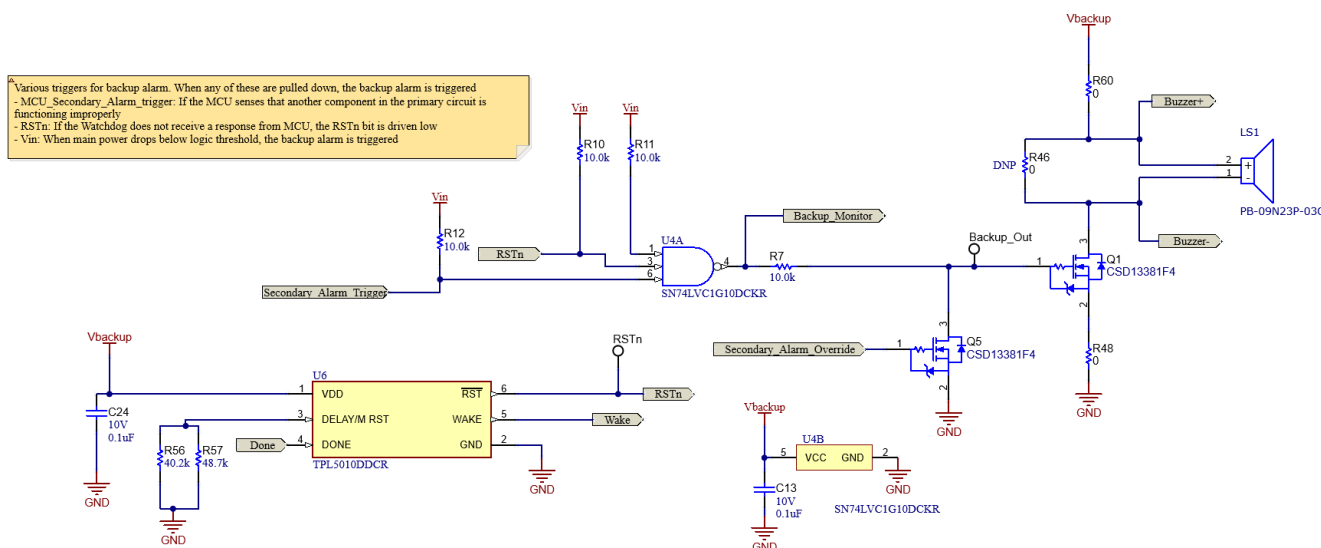


Figure 2-4. Backup Alarm Circuit

2.2.4 Supercapacitor Charging Circuit

Figure 2-5 illustrates the supercapacitor charging and backup power circuit schematic.

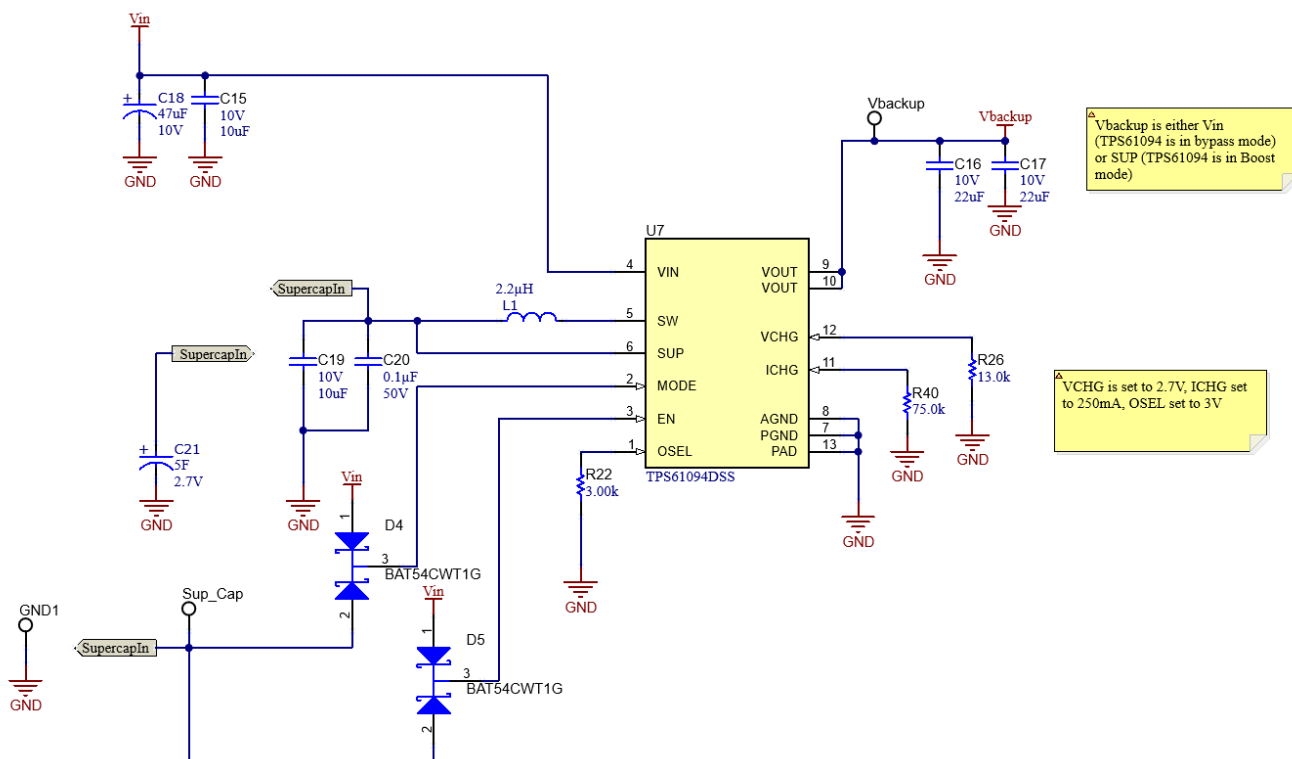


Figure 2-5. Supercapacitor Charging Circuit

Due to the 0.7 V minimum needed for the supercapacitor voltage to operate, some of the supercapacitor energy capacity is unavailable.

Equation 2 shows the usable supercapacitor energy storage for supercapacitors used that are rated for less than 5 V.

$$E_{\text{Joules}} = \frac{1}{2} \times C \times V^2 - \frac{1}{2} \times C \times (0.7 \text{ V})^2 \quad \left\{ \text{Supercapacitor } V_{\text{CHG}} < 5 \text{ V} \right\}$$

$$E_{\text{Joules}} = \frac{1}{2} \times C \times V^2 - 0.245 \times C \quad \left\{ \text{Supercapacitor } V_{\text{CHG}} < 5 \text{ V} \right\} \quad (2)$$

In this design the supercapacitor has a voltage of 2.7 V and a capacitance of 5 F, offering 17 joules of energy storage. The maximum supercapacitor charging voltage is 5 V with the TPS61094. Equation 3 shows the usable energy storage if the chosen supercapacitor is rated for 5 V or greater.

$$E_{\text{Joules}} = \frac{1}{2} \times C \times (5 \text{ V})^2 - 0.245 \times C \quad \{\text{Supercapacitor } V_{\text{CHG}} \geq 5 \text{ V}\}$$

$$E_{\text{Joules}} = 12.255 \times C \quad \{\text{Supercapacitor } V_{\text{CHG}} \geq 5 \text{ V}\} \quad (3)$$

As Table 2-1 shows, V_{IN} must be 100 mV greater than the target V_{OUT} to enter auto buck mode and charge the supercapacitor. For this reason, the target V_{OUT} was set to 3 V. This was set by connecting a 3-k Ω resistor to the OSEL pin. Once the input voltage V_{IN} drops below the target voltage, the boost operation begins. See Figure 3-7 and Figure 3-8 for the power transition waveforms.

Table 2-1. Operation Modes

MODES	EN	MODE	BYPASS	BOOST	BUCK	FUNCTION
Forced bypass	0	0	√	×	×	Turn on bypass MOSFET, turn off boost or buck, $V_{\text{OUT}} = V_{\text{IN}}$
True shutdown	0	1	×	×	×	Bypass disconnect, turn off boost or buck, $V_{\text{OUT}} = 0 \text{ V}$
Forced buck	1	0	√	×	√	Buck enabled, turn on bypass MOSFET, $V_{\text{OUT}} = V_{\text{IN}}$ while charging the supercapacitor or backup battery
Auto buck or boost	1	1	√	×	√	Buck enable, when $V_{\text{IN}} > \text{target } V_{\text{OUT}} + 100 \text{ mV}$ and $V_{\text{OUT}} > \text{target } V_{\text{OUT}}$, supercapacitor is charged by buck
	1	1	√	√	×	Boost and bypass enabled; when $V_{\text{OUT}} + 100 \text{ mV} > V_{\text{IN}} > \text{target } V_{\text{OUT}}$ and $V_{\text{OUT}} = \text{target } V_{\text{OUT}}$, V_{OUT} is from both V_{IN} through bypass and supercap by boost.
	1	1	×	√	×	Boost enable; when $V_{\text{IN}} < \text{target } V_{\text{OUT}}$, V_{OUT} is powered from supercapacitor by boost.

2.2.5 Software Flow Chart

Figure 2-6 illustrates the software flow chart.

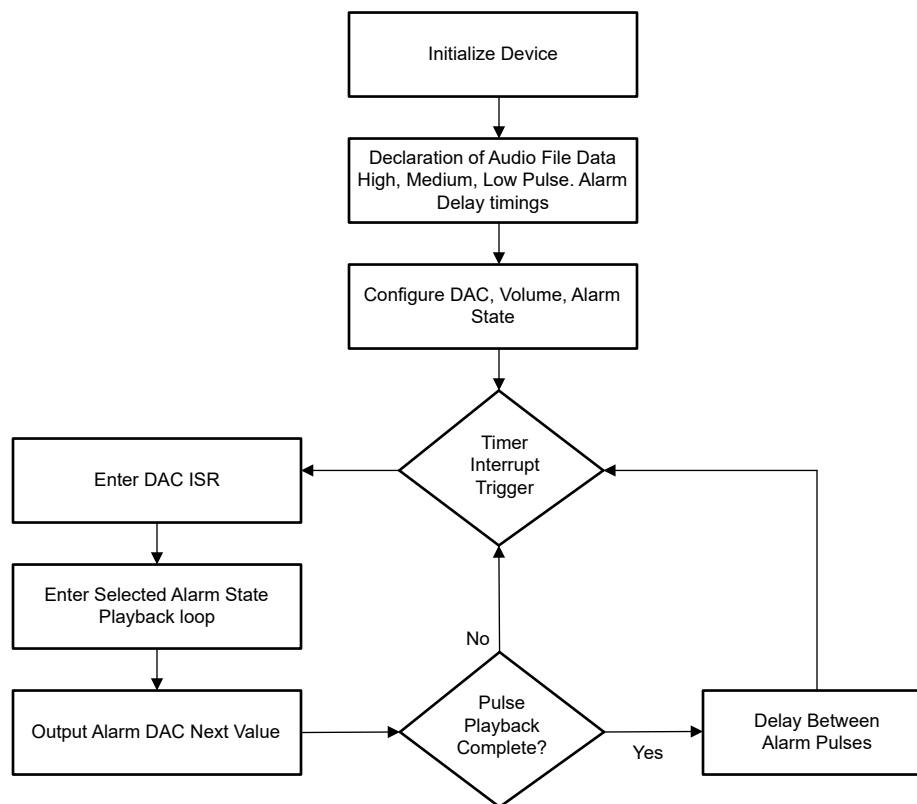


Figure 2-6. Software Flow Chart

2.3 Highlighted Products

2.3.1 MSPM0G150x

MSPM0G150x microcontrollers (MCUs) are part of the MSP highly-integrated, ultra-low-power 32-bit MCU family based on the enhanced Arm® Cortex®-M0+ 32-bit core platform operating at up to 80-MHz frequency. These cost-optimized MCUs offer high-performance analog peripheral integration, support extended temperature ranges from -40°C to 125°C , and operate with supply voltages ranging from 1.62 V to 3.6 V.

The MSPM0G150x devices provide up to 128KB embedded flash program memory with built-in error correction code (ECC) and up to 32KB SRAM with ECC and hardware parity option. These MCUs also incorporate a memory protection unit, 7-channel DMA, math accelerator, and a variety of high-performance analog peripherals such as two 12-bit 4-MSPS ADCs, configurable internal shared voltage reference, one 12-bit 1-MSPS DAC, three high speed comparators with built-in reference DACs, two zero-drift zero-crossover op amps with programmable gain, and one general-purpose amplifier. These devices also offer intelligent digital peripherals such as two 16-bit advanced control timers, five general-purpose timers (with one 16-bit general-purpose timer for QEI interface, two 16-bit general-purpose timers for STANDBY mode, and one 32-bit general-purpose timer), two windowed-watchdog timers, and one RTC with alarm and calendar modes. These devices provide data integrity and encryption peripherals (AES, CRC, TRNG) and enhanced communication interfaces (four universal asynchronous receivers and transmitters (UART), two I2C, two serial peripheral interfaces (SPI)).

The TI MSPM0 family of low-power MCUs consists of devices with varying degrees of analog and digital integration allowing for customers find the MCU that meets the needs of their project. The MSPM0 MCU platform combines the Arm Cortex-M0+ platform with a holistic ultra-low-power system architecture, allowing system designers to increase performance while reducing energy consumption.

2.3.2 TPS61094

The TPS61094 is a 60-nA I_Q boost converter with supercapacitor management. The device provides a power supply design for smart meter and supercapacitor backup power applications.

The TPS61094 has a wide input voltage range and output voltage up to 5.5 V. When the TPS61094 works in buck mode and charges the supercapacitor, the charging current and the termination voltage are programmable with two external resistors. When the TPS61094 works in boost mode, the output voltage is programmable with an external resistor.

During automatic buck or boost mode ($\text{EN} = 1$, $\text{MODE} = 1$), when the input power supply is applied, the device bypasses the input voltage to the output while it is capable of charging a backup supercapacitor. When the input power supply is disconnected or lower than the output target voltage, the TPS61094 enters boost mode and regulates output voltage from a backup supercapacitor. The TPS61094 consumes 60-nA quiescent current in this mode.

The TPS61094 supports true shutdown mode ($\text{EN} = 0$, $\text{MODE} = 1$) and the forced bypass mode ($\text{EN} = 0$, $\text{MODE} = 0$). In true shutdown mode, the TPS61094 completely disconnects the load from the input supply. When supporting forced bypass mode, the TPS61094 connects the load to the input voltage directly through a bypass switch and only consumes 4-nA current to achieve long battery life.

2.3.3 TPA6211A1

The TPA6211A1 is a 3.1-W mono fully-differential amplifier designed to drive a speaker with at least 3- Ω impedance while consuming only 20-mm² total printed-circuit board (PCB) area in most applications. The device operates from 2.5 V to 5.5 V, drawing only 4 mA of quiescent supply current. The TPA6211A1 is available in the space-saving 3-mm $\times$ 3-mm SON (DRB) and the 8-pin MSOP-PowerPAD™ (DGN) integrated circuit packages.

Features like -80-dB supply voltage rejection from 20 Hz to 2 kHz, improved RF rectification immunity, small PCB area, and a fast start-up with minimal pop makes the TPA6211A1 an excellent choice for PDA and smartphone applications.

3 Hardware, Software, Testing Requirements, and Test Results

3.1 Hardware Requirements

Table 3-1 details the required test equipment.

Table 3-1. Equipment Used for Testing

EQUIPMENT	RATING	DESCRIPTION
DC Power Supply	3.3 V, 1 A	Device input power
Speaker	4 Ω	Primary Alarm Sound Output
SPI Flash Programmer	-	For programming custom audio to SPI flash
MSPM0 Programmer	-	Any MSPM0 LaunchPad™ or XDS110 debug programmer

3.2 Software Requirements

3.2.1 Software Overview

3.2.1.1 Programming MSPM0 MCU

To program the MCU, connect the MSPM0 programmers GND, NRST, SWDIO, and SWCLK pins to the J3 connector. Connect an external 3.3-V DC power supply to the V_{IN} and GND connections on the alarm board. Once the programmer is connected to the host computer, program it with the [Code Composer Studio™](#) integrated development environment (IDE).

3.2.1.2 Programming External SPI Flash

An SPI flash programmer is required to write audio to the external flash. Connect the programmer to the J2 connector. Make sure that the SPI programmer is operating at 3.3 V before flashing the audio.

3.3 Test Setup

Table 3-2 shows the TIDA-010264 board connections.

Table 3-2. TIDA-010264 Board Connections for Testing

CONNECTOR	DESCRIPTION
V_{IN} , GND	Connected to DC power supply, 3.3 V
SPK+, SPK–	Connected to 4- Ω speaker
SPI Flash Programmer	Connected to J2
MSPM0 Programmer	Connected to J3

3.4 Test Results

This section describes the test procedures used to verify the functionality of this design.

3.4.1 Primary Alarm Waveforms

Figure 3-1 shows the waveform measured at the output of the MSPM0 12-bit DAC, while playing the high-alarm state. Key waveform characteristics including the fundamental frequency, rise time, fall time, pulse spacing, and more were measured internally to meet the IEC60601-1-8 requirements.

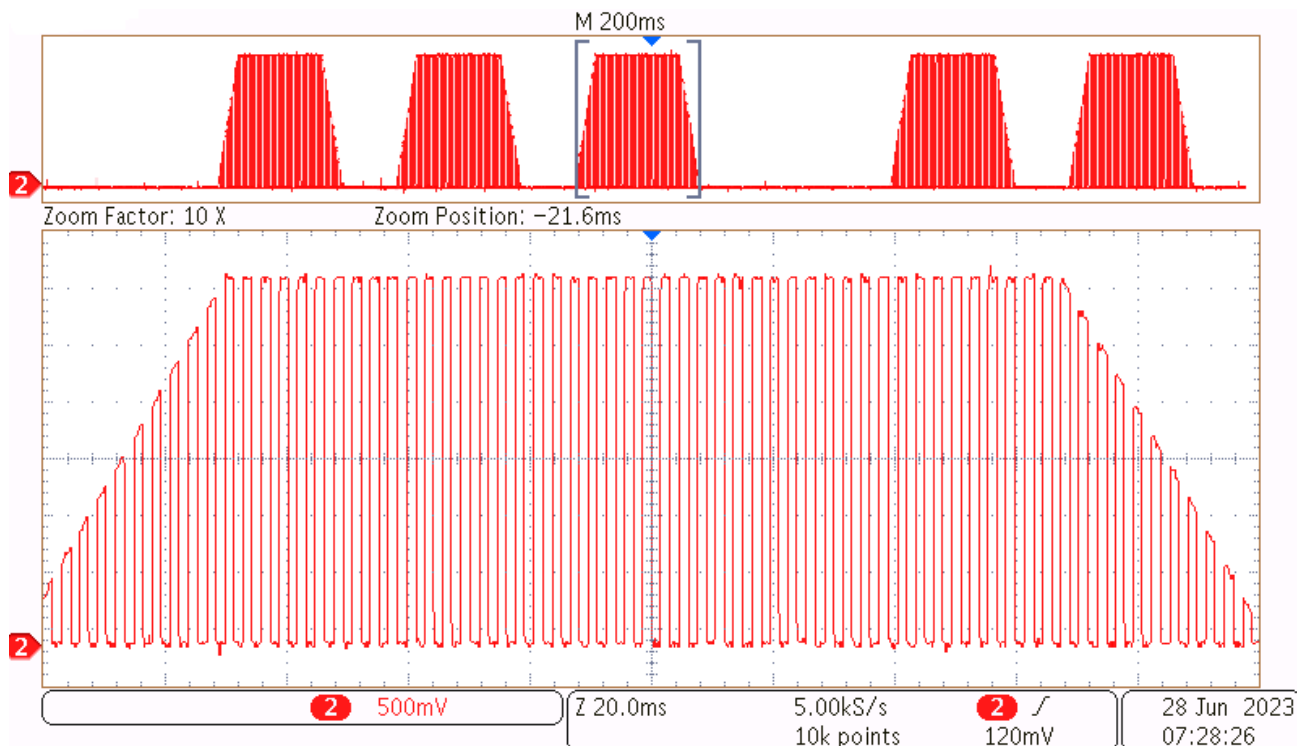


Figure 3-1. High-Alarm State DAC Waveform

Figure 3-2 shows the high-priority alarm waveform measured from the positive and negative terminals of the speakers.

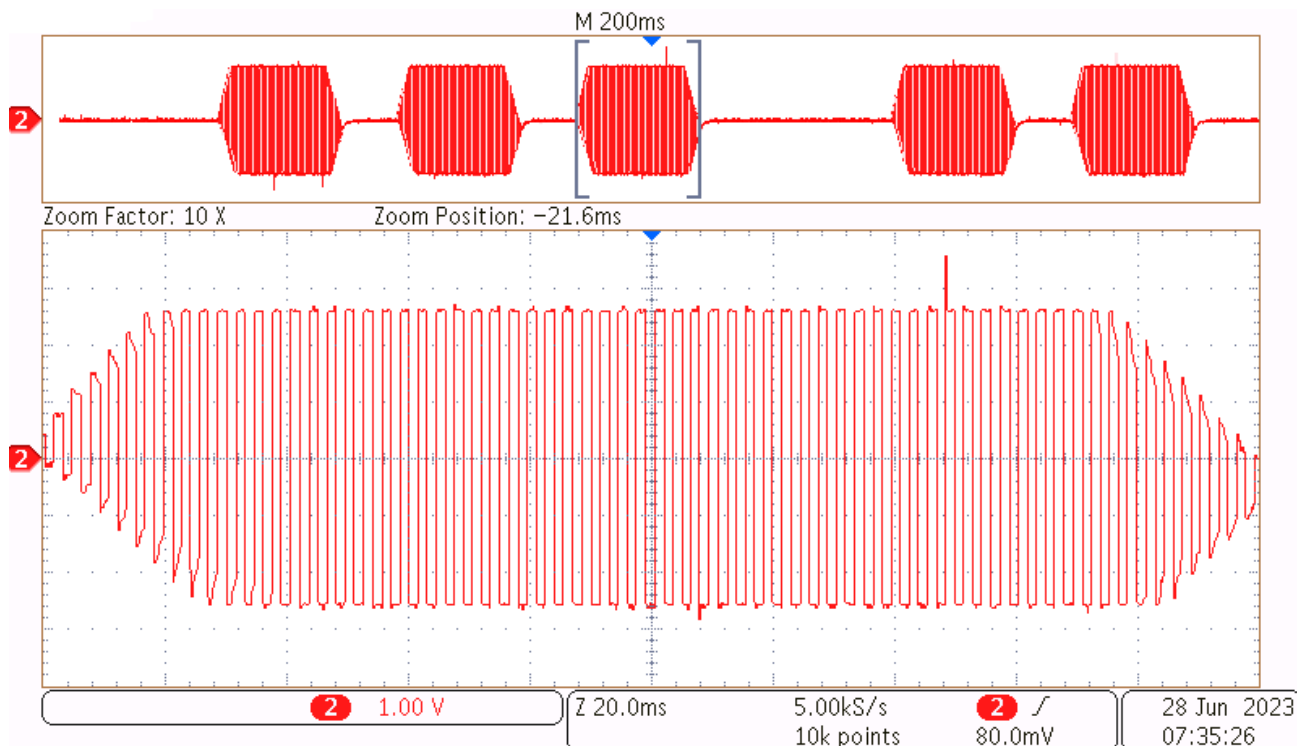


Figure 3-2. High-Alarm State Speaker Waveform

Figure 3-3 shows an example custom audio waveform measured from the positive and negative terminals of the speakers.

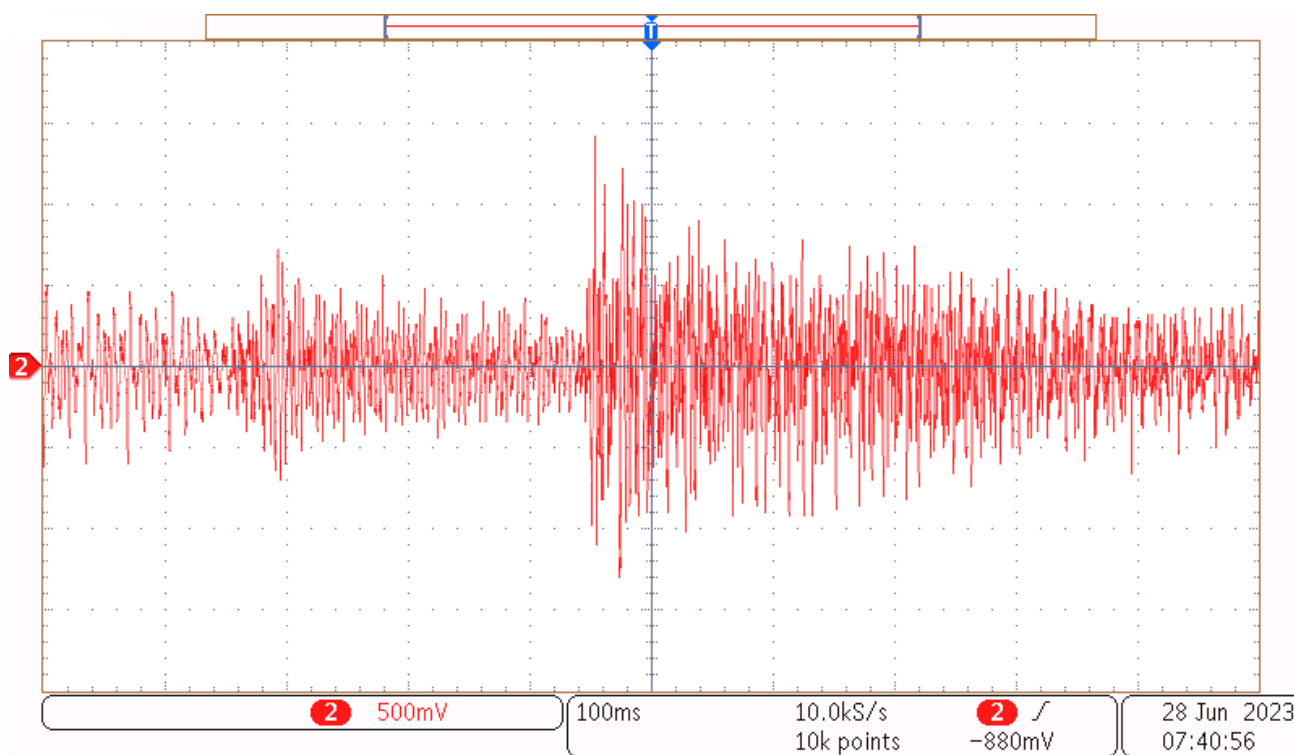


Figure 3-3. Custom Audio Speaker Waveform

3.4.2 Primary Alarm Harmonic Testing

Figure 3-4 shows the harmonic content of the high alarm state. To meet the IEC60601-1-8 requirements, at least 4 harmonics need to be +/- 15 dB from the amplitude of the fundamental frequency. Eight harmonics are measured within the required range for this high alarm state test.

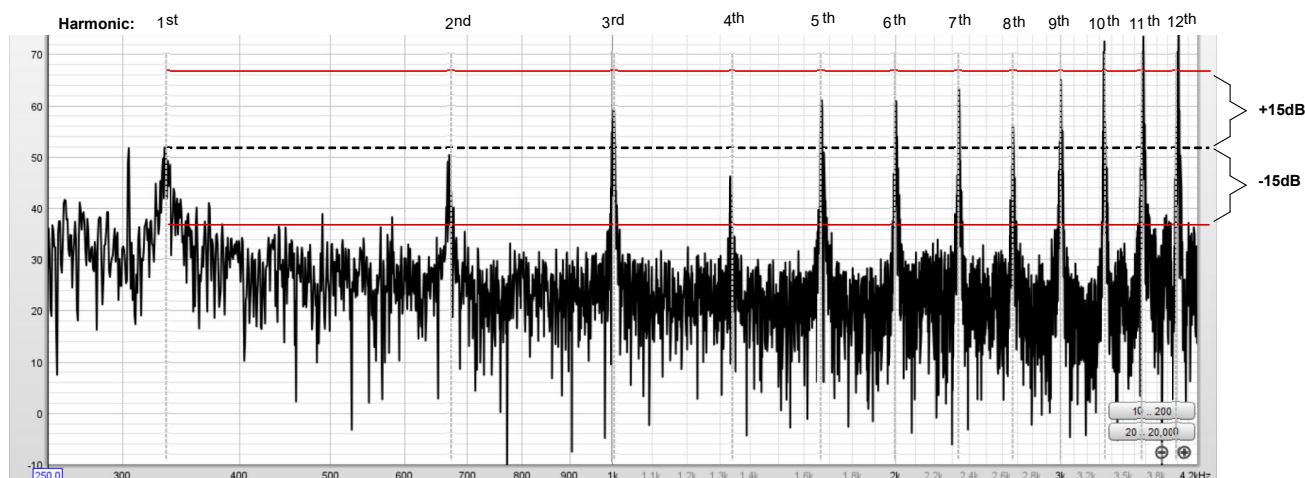


Figure 3-4. Harmonic Test High Alarm State

3.4.3 Coincidence Detection

The coincidence detection circuit was tested by measuring the MSPM0G150x internal op-amp output. The pulses shown in [Figure 3-5](#) show the high alarm state waveform through the measurement of the TPA6211A1 current consumption. If the speaker is faulty (for example, disconnected), the current waveform dramatically reduces.

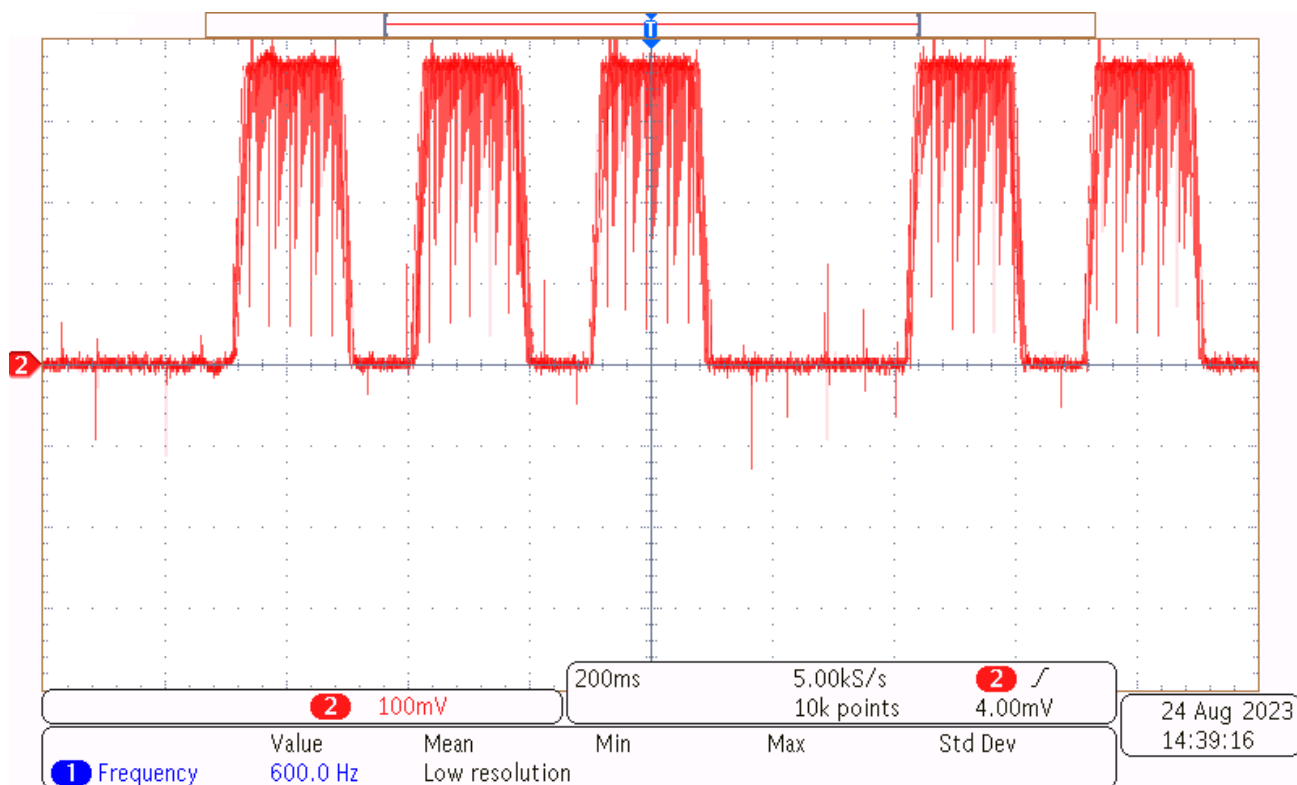


Figure 3-5. High-Alarm State Current-Sense Waveform

[Figure 3-6](#) shows the analog signal output of the microphones during a high alarm state. This signal can be digitized by the ADC of the MSPM0, allowing for acoustic measurements of the primary alarm signal. Ambient noise levels can also be measured by the microphone, allowing for the adjustment of the primary alarm volume levels.

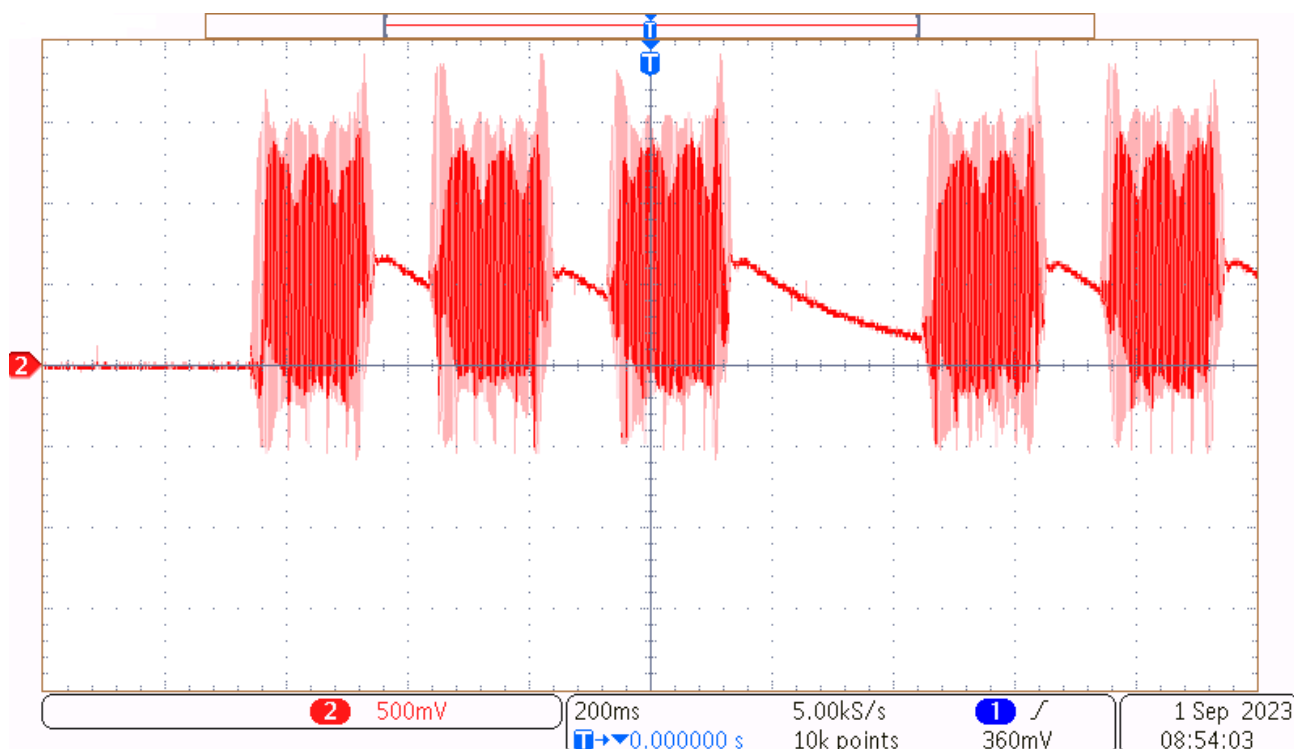


Figure 3-6. High-Alarm State Microphone Waveform

3.4.4 Backup Power Transition

Figure 3-7 shows the transition from an external 3.3-V power source to the 3-V supercapacitor backup source.

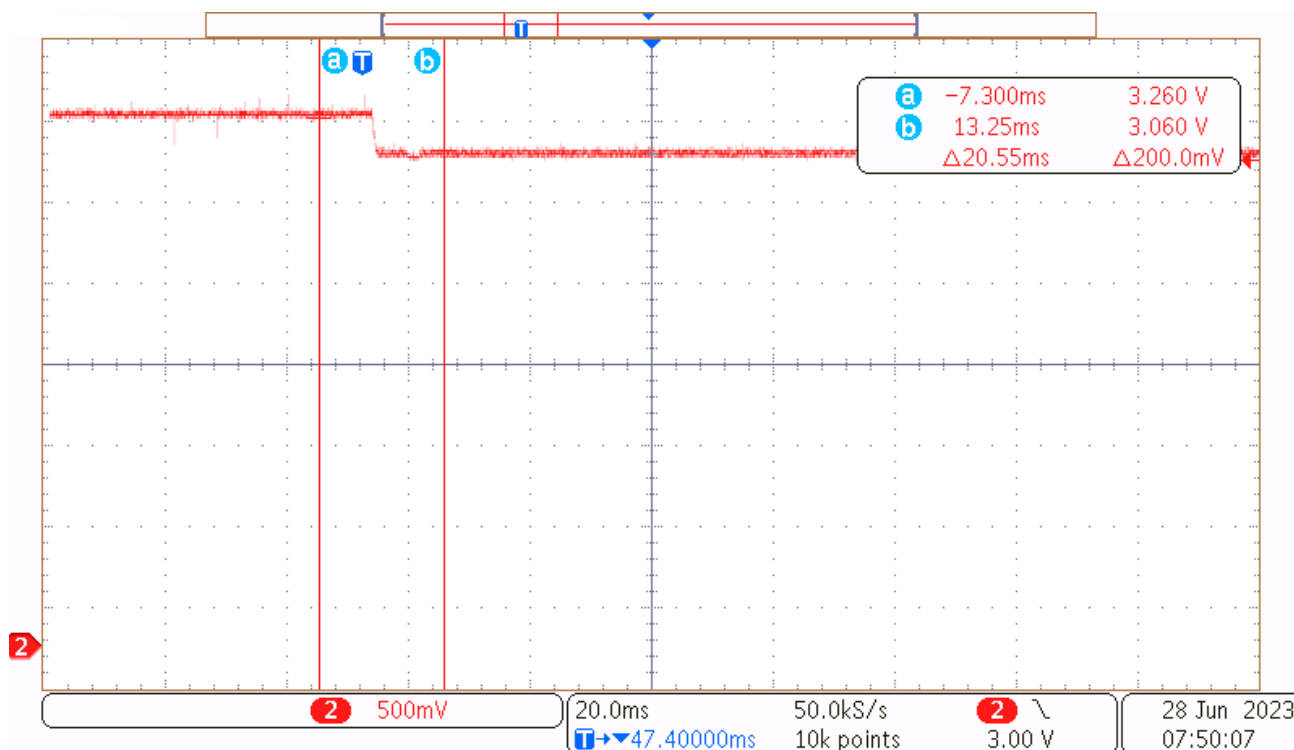


Figure 3-7. External Power to Backup Power

Figure 3-8 shows the transition from the 3-V supercapacitor backup mode back to the external 3.3-V power source.

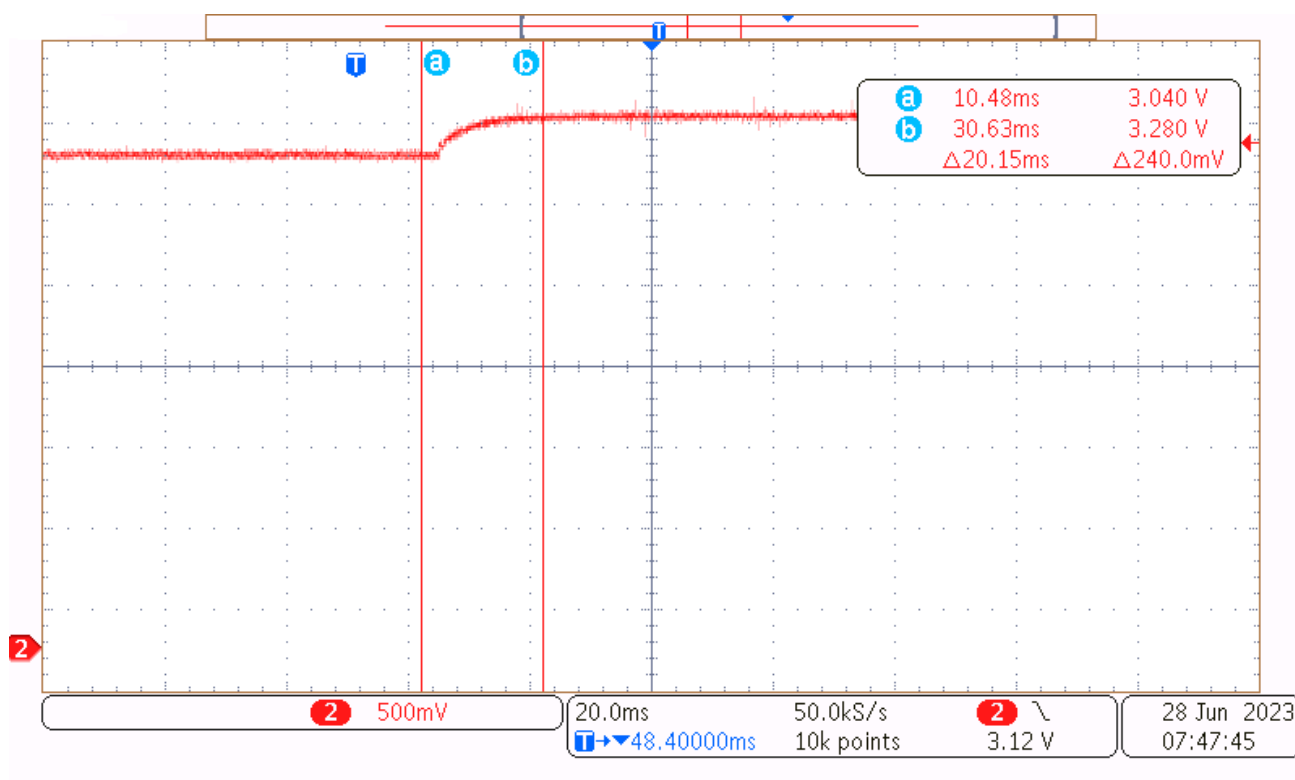


Figure 3-8. Backup Power to External Power

3.4.5 Alarm Sound Levels and Backup Alarm Runtime

Table 3-3 shows the primary and backup alarm sound levels in dBA measured one meter away from the source. The table also shows the runtime of the alarm for a given condition, such as the series resistance connected to the backup alarm buzzer.

Table 3-3. Primary and Backup Alarm Sound Levels

ALARM TYPE	SOUND LEVEL (dBA AT 1 m)	RUNTIME
Primary	73.3	Continuous (line power)
Backup (0-Ω series resistance)	68.8	2 minutes 50 seconds from 2.7-V, 5F supercapacitor
Backup (43-Ω series resistance)	66.3	3 minutes 52 seconds from 2.7-V, 5F supercapacitor

4 Design and Documentation Support

4.1 Design Files

4.1.1 Schematics

To download the schematics, see the design files at [TIDA-010264](#).

4.1.2 BOM

To download the bill of materials (BOM), see the design files at [TIDA-010264](#).

4.2 Tools and Software

Tools

Code Composer Studio™

Code Composer Studio is an integrated development environment (IDE) for TI's microcontrollers and processors. Code Composer Studio comprises a suite of tools used to develop and debug embedded applications. Code Composer Studio is available for download across Microsoft® Windows®, Linux®, and macOS® desktops. This product can also be used in the cloud by visiting the [TI Developer Zone](#).

Software

TIDA-010264- MSPM0G150x-FW

With this downloadable firmware, the onboard MSPM0G150x on the TIDA-010264 reference design allows for an IEC60601-1-8 compliant medical alarm design with the ability to play standard alarms and custom audio.ilit

4.3 Documentation Support

1. Texas Instruments, [MSPM0-Based Medical Alarm Design](#) application brief
2. Texas Instruments, [Hardware-Based Smart DAC Medical Alarm Design](#) application brief
3. Texas Instruments, [Demystifying Medical Alarm Designs With Smart DACs](#) application brief
4. Texas Instruments, [Demystifying medical alarm designs, part 1: IEC60601-1-8 standard requirements](#) TI E2E™ forum
5. Texas Instruments, [Demystifying medical alarm design, part 2: Design inputs and existing techniques](#) TI E2E™ forum
6. Texas Instruments, [TPS61094 60-nA Quiescent Current Boost Converter With Supercap Management](#) data sheet
7. Texas Instruments, [MSPM0G150x Mixed-Signal Microcontrollers](#) data sheet
8. Texas Instruments, [TPA6211A1 3.1-W Mono Fully Differential Audio Power Amplifier](#) data sheet
9. Texas Instruments, [TPL5010 Nano-Power System Timer With Watchdog Function](#) data sheet

4.4 Support Resources

[TI E2E™ support forums](#) are an engineer's go-to source for fast, verified answers and design help — straight from the experts. Search existing answers or ask your own question to get the quick design help you need.

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